PHILIPS

K140772

APR 2 5 2014

7. 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment registration number: 3003768251	
Contact Person:	Gerold Schwarz Regulatory Affairs Manager, North America Phone: +49 40 5078-1116 Fax: +49 40 5078-2022 E-mail: gerold.schwarz@philips.com.	
Device Name:	**Philips *Eleva Workspot***	
Classification (primary):	Classification Name:	Stationary x-ray system
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	MQB
Classification (secondary):	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21CFR 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	LLZ (system, image processing)
Predicate Devices:		
Primary Predicate Device	Trade Name:	Philips XD-S Direct Radiography Workstation/Package
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K063781 - January 5, 2007
	Classification Name (primary):	Stationary x-ray system
	Classification Regulation	21 CFR 892.1680

	(Primary):	
	Classification Panel (primary):	Radiology
	Device Class (primary):	Class II
	Product code (primary):	MQB
	Classification Name (secondary):	Picture archiving and communications system
	Classification Regulation (secondary):	21CFR 892.2050
	Classification Panel (secondary):	Radiology
	Device Class (secondary):	Class II
	Product code (secondary):	LLZ (system, image processing)
Secondary Predicate Device	Trade Name:	DX-D Imaging Package
	Manufacturer:	Agfa HealthCare N.V. Septestraat 27 B-2640 Mortsel Belgium
	510(k) Clearance:	K122736 - March 11, 2013
	Classification Name:	Stationary x-ray system
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	MQB

Device description:

The Philips *Eleva Workspot* is a workstation (computer, keyboard, display, mouse), combined with a flat solid state X-ray detector. It is designed to be used with the following set of flat solid state X-ray detectors:

- Philips Pixium 4600
- Philips Wireless Portable Detector FD-W17
- Philips Pixium 4343RC

It is used by the operator to preset examination data and to generate process and handle digital X-ray images. The Philips *Eleva Workspot* will be used as a common software platform in the following currently marketed Philips X-ray systems:

- Philips *Digital Diagnost* (K131483 – October 7, 2013),
- *MobileDiagnost* (K111725 – July 19, 2011),
- Philips *PCR Eleva* (K093355– October 28, 2009),
- Philips *EasyDiagnost Eleva (K031535 – September 6, 2006), and*
- Philips *BuckyDiagnost (K945278 – December 29, 1994).*

As a part of a radiographic system, the Philips *Eleva Workspot* is intended to acquire, process, store, display, and export digital radiographic images. The Philips *Eleva Workspot* is also intended for clinical situations where physicians decide not to use an anti-scatter grid in situations where patients require bedside chest AP digital radiographs.

There is a standalone version with minimal integration into the X-ray system. This standalone version does not connect to a solid state X-ray detector. Instead, it is intended to connect to a Philips PCR x-ray cassette reader. With the fully integrated version, the workstation screen also provides displays area and controls for X-ray generator control. The workstation computer can also host parts of the system control software.

The device modification employs an additional software algorithm (referred to as "*SkyFlow*" in this premarket notification) to post-process digital radiographs that are generated in clinical situations where physicians decide not to use an anti-scatter grid in critical care departments of hospitals such as ICU and Emergency, where patients require bedside chest AP digital radiographs. The software modifications enhance image contrast, producing images that have similar detail contrast as images acquired with an anti-scatter grid. Image quality and detail detectability improvements depend on the clinical task, patient size, anatomical location, and clinical practice. The additional *SkyFlow* software feature is an optional and reversible image processing option that is not required by the Philips *Eleva Workspot* to reach its intended use.

Indications for Use:

The Indication for Use of the Philips *Eleva Workspot* is identical to that of the currently marketed and predicate device, Philips XD-S Direct Radiography Workstation/Package, K063781 – January 5, 2007, and is as follows:

> *As a part of a radiographic system, the* Philips *Eleva Workspot is intended to acquire, process, store, display, and export digital radiographic images. The* Philips *Eleva Workspot is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.*

Fundamental Scientific

The Philips *Eleva Workspot* employs the same basic construction and fundamental scientific technology as provided with the currently

Technology:	marketed and predicate device, Philips XD-S Direct Radiography Workstation/Package, K063781 – January 5, 2007 with regards to the functionality of the following: image receptor type, image processor, automatic image processing, manual image processing, advanced image processing, image export (interfaces), X-ray generator integration and the use of standard monitors. Based on the information provided above, the Philips *Eleva Workspot* is considered substantially equivalent to the currently marketed and predicate device, Philips XD-S Direct Radiography Workstation/Package, K063781 – January 5, 2007 in terms of fundamental scientific technology.
Summary of Non-Clinical Performance Data:	The Philips *Eleva Workspot* complies with the following international and FDA-recognized consensus standards: • IEC 62304 *Medical device software – Software life cycle processes* (2006) • IEC 62366 *Application of usability engineering to medical devices* (2007) • ISO 14971 *Application of risk management to medical devices* (2007) Non-clinical software verification and validation tests have been performed with regards to the intended use, technical claims, requirements specifications and risk management results. The non-clinical software verification and validation test results demonstrate that the Philips *Eleva Workspot* complies with international and FDA-recognized consensus standards and meets the acceptance criteria and is adequate for its intended use. Therefore, the Philips *Eleva Workspot* is substantially equivalent to the currently marketed device, Philips XD-S Direct Radiography Workstation/Package, K063781 – January 5, 2007 in terms of safety and effectiveness.
Summary of Clinical Data:	The Philips *Eleva Workspot* did not require clinical studies since substantial equivalence to the currently marketed and predicate device was demonstrated with the following attributes: • Design features; • Indication for use; • Fundamental scientific technology; • Non-clinical performance testing including validation; and • Safety and effectiveness.
Summary of Substantial Equivalence	The Philips *Eleva Workspot* is substantially equivalent to the currently marketed and predicate device, Philips XD-S Direct Radiography Workstation/Package, K063781 – January 5, 2007 in terms of design

Conclusion: features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304, IEC 62366 and ISO 14971. The results of these tests demonstrate that Philips *Eleva Workspot* met the acceptance criteria and is adequate for this intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Philips Medical Systems DMC GMBH
Gerold Schwarz
ROENTGENSTRASSE 24-26
HAMBURG 22335
GERMANY

Re: K140771
Trade/Device Name: Philips Eleva Workspot
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, LLZ
Dated: March 21, 2014
Received: March 27, 2014

Dear Mr. Schwarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

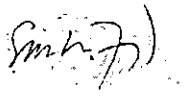
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140771

Device Name

Philips Eleva Workspot

Indications for Use *(Describe)*

As a part of a radiographic system, the Philips Eleva Workspot is intended to acquire, process, store, display, and export digital radiographic images. The Philips Eleva Workspot is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

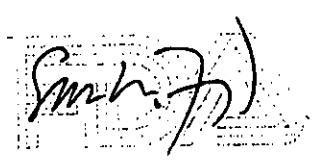
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."